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PROPOSED DATA REQUIREMENTS

2,4-D

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Oncogenicity

- o Standard oral exposure studies of acid in rats and mice.
- o Subcutaneous or dermal exposure study of isooctyl ester in mice.

Reproduction

- o Multigeneration study to establish NOELS for the acid form of 2,4-D in one species.
- o Teratology/fetotoxicity studies to establish NOELS in rats for:
  - Acid
  - Butoxy Propyl Ester
  - Alkanol Amine
  - Isopropyl Ester
  - Dichlorophenol metabolite

Mutagenicity

No requirements.

Neurotoxicity

- o Subchronic neurotoxicity studies in dogs, rats, and chickens by oral route (including a recovery period) for acid and dimethylamine.
- o Subacute dermal neurotoxicity study in dogs.

Metabolism

- o Standard metabolism studies in dogs and rats for acid, isooctyl ester and PGBE.
- o Standard metabolism study in pregnant rats for acid, isooctyl ester, and PGBE.

Acute Toxicity

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- Oral LD_{50} in rat for each formulation.

  Dermal LD_{50} in rat for each formulation.

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Dermal Absorption

- Radiolabeled dermal absorption study in an appropriate species for each formulation meeting one of the following criteria:

  - It contains an active ingredient which has shown fetotoxic effects at relatively low doses (this includes all 2,4-D forms included in the teratology study request plus the isooctyl ester and PGBE).

  - Its use is likely to result in dermal exposure to human females.